wherein the polyclonal, monospecific antibodies are present in a concentration to achieve a verotoxin neutralization titer of equal to or greater than 1:8.

REMARKS

I. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 10-17 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner states that the specification does not reasonably provide enablement for the method of the claims comprising a method of preventing infection and disease from verotoxin-producing bacteria in animals by administrating a composition comprising polyclonal, monospecific antibodies isolated from natural animal serum (claim 10), wherein the composition is administered in a dose of from about 1 g to about 30 g of plasma protein per day (claim 13).

Claim 10 has now been amended to remove the phrase "preventing infection and disease from verotoxin-producing bacteria" and to state that the method is used in "reducing the number of verotoxin-producing organisms in the intestine

and colon of animals." Support for this amendment is found in the specification on p. 4, para. 4, and Example 1.

Example 1 demonstrates that administration of the animal serum product of this invention is effective in reducing verotoxin concentrations in the colon, as exemplified by the measured verocytotoxicity of animals challenged with verotoxin-producing organisms versus challenged animals receiving the animal serum Ig concentrate of the claimed invention. While treated animals had verocytotoxicity levels ranging from 4-16, untreated animals had a verocytotoxicity level of 4096. Thus, animals treated with the claimed composition had antitoxin activity at least 256 times greater than that of untreated animals.

The Examiner has expressed skepticism that the composition of claim 10 is enabled for the feeding of any animal serum to any animal. (Office Action, p. 3). Claim 10 has further been amended to state that the composition includes polyclonal, monospecific antibodies to verotoxin-producing organisms and their toxins. Support for this amendment is found on p. 7, para. 1 of the specification. Newly added claims 21 and 24 further specify that the antibodies are present in a concentration to achieve a verotoxin neutralization titer of equal to or greater than 1:8. Example 1 demonstrates that this concentration of

antibodies is effective in reducing the concentration of verotoxin-producing organisms. (Spec., p. 13, para. 3).

New claims 23 and 24 further specify the preferred types of sources of animal serum, namely bovine and porcine. (Spec. p. 9, third para.). While these sources of animal serum are preferred for purposes of convenience, the serum source may be from any animal that has serum (Spec. p. 9), so long as the serum includes polyclonal, monospecific antibodies to verotoxin-producing organisms and their toxins, as required by the claims.

With respect to the type of animal to which the animal serum is administrated, the invention may be used to decrease the number of verotoxin-producing organisms in any animals, including humans. (Spec. pp. 8-9). As noted in the disclosure, the claimed serum product is effective in treating humans that have ingested food or water contaminated with Shigella, E. coli 0157:H7 and/or other VTEC. (Spec. p. 9). It is also effective in increasing weight gain and growth in pigs, other food animals, and companion animals. (Spec. p. 9, Example 1). While Applicants' specific test results pertain only to pigs, it is respectfully submitted that one of ordinary skill in the art would reasonably believe that the present invention would also have utility in other animal species.

Further, new claims 22-24 specify that the claimed composition is preferably administered to animals selected from the group consisting of mammals and poultry.

It is therefore respectfully submitted that it would not take a person skilled in the art an undue amound ot experimentation to practice the claimed invention. Claims 10-17 and new claims 21-24 are therefore enabled.

II. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

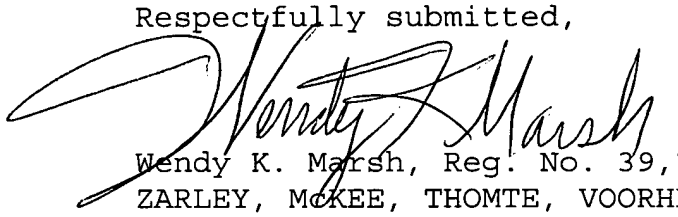
Claims 10-17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite due to the use of the term "natural serum." Applicant has now removed the word "natural" prior to serum, thereby alleviating this objection.

III. Conclusion

For all of the above-stated reasons, Applicant respectfully requests allowance of the application.

Enclosed please find a check for $78 for the addition of one independent claim. If this amount is insufficient, please consider this a request to debit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,



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